REMARKS

Reconsideration of the present application, as amended, is respectfully requested. Applicants undersigned representative expresses appreciation for the courtesy of a telephone interview with the Examiner, conducted on May 7, 2009. During this interview it was agreed that the claim term, "mixture" was supported by the specification, and that this amendment, and the other claim amendments would likely not introduce new grounds for examination and would most likely be entered by the Examiner after Final.

A. Claim Amendments

The claims are amended, without prejudice, to more particularly set forth that which Applicants consider to be their invention. The claims are amended to replace the term, "vaccine" with "mixture" (plasmid or adenovirus mixtures, if based on claims 1 or 16, respectively) and to restore the transition phrase "containing" in place of "consisting essentially of." Claims 1, 16, 38 and 39 are amended to include the elements of dependent claims 4 and 19. Claims 4 and 19 are now cancelled as redundant. Withdrawn claims 30-35 and 40 are amended in conformity to the other claims, based on the statement by the Examiner that the method claims are subject to rejoinder should the product claims be found allowable (Office Action, page 3, lines 3-6).

"Mixture" is supported, for example, at page 18, lines 13-17, page 30, lines 11-16. These sections confirm that combinations of multiple DNA components are at least considered to be mixtures. The terms "plasmid" or "adenovirus" are employed along with the term "mixture" ("plasmid mixture" or "adenovirus mixture") in order to avoid confusion in withdrawn/amended method claims 30 et seq. Support for these respective terms is submitted to be self-evident in the body of respective claims 1 and 16, which require combinations of the enumerated plasmids or recombinant adenoviruses, respectively. As noted by the Examiner in the Office Action, page 3, lines 1-6, the method claims are subject to rejoinder.

B. Rejection Under 35 U.S.C. 112, first paragraph

Beginning at page 3 of the Office Action, the Examiner has maintained the rejection of claims 1, 2, 4-17 and 19-29, 38 and 39, again alleging that the claims do not fulfill the enablement requirement of 35 U.S.C., first paragraph.

Applicants respectfully disagree. Applicants appreciate the telephone interview granted

to their undersigned representative on December 11, 2008. During that interview, the Examiner confirmed that this rejection was based on the use of the term, "vaccine" in claim 1, et seq. The Examiner took the position that the conventional meaning of vaccine included use as a preventative, and that the data supported a "therapeutic" but not a preventative vaccine. The Examiner expanded on her statement on page 3 of the Office Action, that an "immunogenic composition" is enabled, and that removing the term, "vaccine," would address this ground of rejection under 35 U.S.C. 112, first paragraph. In the interest of expeditious prosecution, and without prejudice to the further prosecution of the vaccine subject matter, Applicants have now amended the claims to replace this term with "mixture".

For all of the above reasons, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

C. <u>The rejection under 35 U.S.C. 102(b)</u>

At page 5 of the Office Action, the Examiner has maintained the previous rejection of pending claims 1, 2, 6, 16, 21, 38 and 39 under 35 U.S.C. 102(b) as allegedly anticipated by Saito et al. (US Patent 5,731,172). The Examiner has also maintained the previous rejection of pending claims 1, 2, 6 and 38 by Tang et al. (US 200410166488 Al).

Applicants respectfully disagree. Saito describes an adenovirus vector which comprises a gene fragment encoding a structural protein consisting of Core, El and E2. However, it is submitted that Saito fails to describe or suggest the invention of, e.g., claims 1 and 16 et seq. Claim 1 requires a mixture of first, second and third plasmids (or adenovirus') as required by claim 1 or 16, respectively, and the claims depending therefrom.

Thus, Saito fails to describe or suggest a mixture comprising a first plasmid (or adenovirus), in which 35-40 amino acids are eliminated from the N-terminal region of the original CORE protein. The elimination of the 35-40 N-terminal Core residues, as amended herein, is believed to render the DNA of the present invention HCV-immunogenic without Core's immunosuppressive function. Saito further fails to describe or suggest a mixture comprising a second plasmid (or adenovirus) containing a DNA fragment encoding a non-structural protein composed of NS3 and NS4 of hepatitis C virus. Further, it is submitted that Saito fails to describe or suggest a third plasmid (or adenovirus) containing a DNA fragment encoding NS5. In particular, Saito neither teaches nor suggests a mixture combining all three

plasmids of claim 1, et seq. nor a mixture combining all three recombinant adenovirus elements of claim 16, et seq.

Tang *et al.* discloses an adenovirus vector comprising a DNA fragment (about 2.7 kb) encoding a structural protein consisting of Core, E1 and E2, and that disclosure suffers from the same clear deficiencies as does Saito. It is submitted that Tang et al. fails to describe or suggest a mixture comprising a first plasmid (or adenovirus), in which 35-40 amino acids are eliminated from the N-terminal region of the original CORE protein as in the instant claims, as amended herein. As noted above, the elimination of the 35-40 N-terminal Core residues is believed to render the DNA of the present invention HCV-immunogenic without Core's immunosuppressive function. Tang further fails to describe or suggest a mixture comprising a second plasmid (or adenovirus) containing a DNA fragment encoding a non-structural protein composed of NS3 and NS4 of hepatitis C virus. Further, it is submitted that Tang fails to describe or suggest a third plasmid (or adenovirus) containing a DNA fragment encoding NS5. In particular, Tang neither teaches nor suggests a mixture combining all three plasmids of claim 1, et seq. nor a mixture combining all three recombinant adenovirus elements of claim 16, et seq.

For all of the above reasons, reconsideration and withdrawal of both rejections under 35 U.S.C. § 102(b) is respectfully requested.

D. Fees

Two claims are newly cancelled, and no new claims are added. Nevertheless, if it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

This response is being filed with a petition for a two-month extension of time and a Notice of Appeal, together with the required **Large Entity** fees via credit card authorization. No further fee is believed to be due. If it is determined that any further fees are due or any overpayment has been made, the Assistant Commissioner is hereby authorized to debit or credit such sum to deposit account 02-2275.

Pursuant to 37 C.F.R. 1.136(a)(3), please treat this and any concurrent or future reply in this application that requires a petition for an extension of time for its timely submission as incorporating a petition for extension of time for the appropriate length of time. The fee associated therewith is to be charged to Deposit Account No. 02-2275.

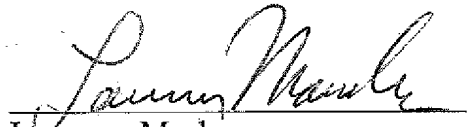
E. Conclusion

In view of the actions taken and arguments presented, it is respectfully submitted that each of the matters raised by the Examiner has been addressed by the present amendment and that the present application is now in condition for allowance.

An early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

LUCAS & MERCANTI, LLP



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